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EXAMINER

RAPILLO, KRISTINE K

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

05/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,968

Applicant(s)

UNDERWOOD ET AL.

Examiner

KRISTINE K. RAPILLO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment submitted November 25, 2008. Claims 1 – 2, 4, 8 – 13, 15 – 16, and 19 are amended. Claims 1 – 4 and 6 – 19 are presented for examination.

Claim Rejections - 35 USC § 101

2. The 35 U.S.C. 101 rejections of claims 1 – 18 are hereby withdrawn based upon the amendment submitted November 25, 2008.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 1 – 4, 6 – 7, 13 – 14, and 16 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trusheim et al., herein after Trusheim (U.S. Patent No. 6,385,589 B1) in view of Goetzke et al., herein after Goetzke (U.S. Publication No. 2002/012866A1).

In regard to claim 1 (Currently Amended), Trusheim teaches a method for administering reductions in health care costs for those participants in a health insurance plan for whom future health care costs may be reduced through intervention ("intervention candidates") comprising computer implemented steps of:
extracting from a database participant data for each of a plurality of participants in the health insurance plan (Figure 1; column 3, lines 18 – 29 and column 4, lines 3 – 19), the participant data

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comprising claims data representing at least one past claim (Figures 29, 30, and 31; column 3, lines 18 – 29; column 16, lines 1 – 13; and, column 21, lines 35 – 41), the past claim being one of a medical claim (Figures 5, 29, and 30) and a pharmacy claim (Figures 5, 29, and 31), wherein:

(a) the claims data representing the medical claim represents one or more of a procedure physically performed on or in connection with the participant (Figure 30), and a diagnosis of a disease or condition physically afflicting the participant (Figure 30 and column 19, lines 47 – 61) where Trusheim uses codes, as is commonly used in the industry, to identify procedures and/or diagnoses, and

(b) the claims data representing the pharmacy claim represents at least in part a drug physically administered to the participant (Figure 31). Trusheim does not explicitly describe administering a drug to a patient, however, it is inherent that a drug which is described for a patient will be administered to the patient;

determining, from the output of the execution of the predictive model program, via the at least one information server (column 11, lines 25 – 26), a first score for an intervention candidate using the participant data, which first score reflects a predicted utilization of future health care services (column 10, lines 24 – 34) where Trusheim provides a score based on an evaluation of the patient (i.e. participant) health situation and the output may be in the form of a letter;

the predictive model program being stored on at least one information server connected to the database (column 4, lines 13 – 19); and,

presenting a graphical user interface for providing to a select individual electronic access to a health care history of the at least one eligible intervention candidate (Figures 7 and 8; column 12, lines 38 – 49 and column 16, lines 45 – 50 where Trusheim discloses a computer system in which a user logs in to access a page presented by the web server) and the result of the comparison (column 21, lines 54 – 60), the graphical user interface including a display of historical information based at least in part on the participant data associated with the at least one eligible intervention candidate and adapted to facilitate intervention in the health care regimen of the at least one eligible intervention candidate based on the

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result of the comparison (Figures 27, 29, 30 and 31) where Trusheim illustrates a patients intervention history, a date range for claim selection, and claims (both medical and pharmaceutical).

Goetzke teaches a method comprising computer implemented steps of: executing a predictive model program using the participant data to generate an output (Figures 10 and 14; paragraphs [0051] and [0075] where Goetzke discloses a predictive model which generates variables for chronic pain; i.e. generating an output), the predictive model program comprising logic to determine a likelihood of occurrence of at least one predetermined future event (paragraphs [0042], [0079], and [0084] through [0096] where a program is used to reach greater certainty about a patient), the event associated with utilization of health care services (paragraphs [0035] and [0082] where the history of prescriptions can be used to determine a utilization pattern), the logic having been created using historical claims data from a sample of individuals (paragraphs [0035] and [0066]).

determining, via the at least one information server (as taught by Trusheim in column 11, lines 25 - 26), a second score for the intervention candidate using the participant data, which second score is a function of the extent of the intervention candidate's prior consumption of a plurality of different predetermined health care services (paragraph [0066] where the patients medical profile is developed from past medical claims to determine a baseline (i.e. score) to determine the appropriate treatment) over a predetermined time interval (Figure 27 and paragraph [0035] where a range can be selected from past medical claims), at least one of the predetermined health care services selected from the group consisting of: a unique drug prescription, an instance of an inpatient admission, an existence of a chronic disease or condition, a unique medical specialty consultation (paragraphs [0029] and [0030] where Goetzke discloses the referral of a patient to a specialist by a primary care physician), an allowed medical claim exceeding a predetermined monetary threshold, and an emergency room visit, the second score reflecting relative desirability of intervention in a health care regimen of the intervention candidate (paragraphs [0067], [0099], and [0106]);

comparing, via the at least one information server (as taught by Trusheim in column 11, lines 25 - 26), the first score against a first threshold value and the second score against a second threshold value

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to identify at least one intervention candidate eligible for intervention and generating a result of such comparison (paragraph [0057]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method comprising computer implemented steps of: executing a predictive model program using the participant data to generate an output, the predictive model program comprising logic to determine a likelihood of occurrence of at least one predetermined future event, the event associated with utilization of health care services, the logic having been created using historical claims data from a sample of individuals, determining, via the at least one information server, a second score for the intervention candidate using the participant data, which second score is a function of the extent of the intervention candidate's prior consumption of a plurality of different predetermined health care services over a predetermined time interval, at least one of the predetermined health care services selected from the group consisting of: a unique drug prescription, an instance of an inpatient admission, an existence of a chronic disease or condition, a unique medical specialty consultation, an allowed medical claim exceeding a predetermined monetary threshold, and an emergency room visit, the second score reflecting relative desirability of intervention in a health care regimen of the intervention candidate; and comparing, via the at least one information server, the first score against a first threshold value and the second score against a second threshold value to identify at least one intervention candidate eligible for intervention and generating a result of such comparison as taught by Goetzke, within the method of Trusheim, with the motivation of providing an efficient and effective health care program while at the same time reducing costs (paragraph [0026]).

In regard to claim 2 (Currently Amended), Trusheim and Goetzke teach a method for administering reductions in health care costs as per claim 1.

Goetzke teaches a method wherein the second score is determined by adding a plurality of values, each of which represents the intervention candidate's consumption predetermined health care service. Goetzke discloses a method where letter designations are used to determine the various pain types, etiology, and pain sites of a patient (paragraphs [0058], [0059], and [0060]).

The motivation to combine the teachings of Trusheim and Goetzke is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 3 (Original), Trusheim and Goetzke teach a method, as per claim 2. Trusheim discloses a method wherein one of the pluralities of values represents the amount of medical claims allowed (column 21, lines 39 – 47). Trusheim et al. discloses a method in which a health care provider can access claims via a web browser thus indicating all claims within a specified date ranges (Figure 30).

In regard to claim 4 (Currently Amended), Trusheim and Goetzke teach a method as per claim 2.

Goetzke teaches a method wherein one of the plurality of values is selected from the group consisting of: a value representing the number of medical specialists that treated the candidate, a value representing the number of inpatient admissions, a value representing the number of chronic diseases for which the candidate was treated, a value representing the number of prescriptions for unique drugs, and a value representing the number of emergency room visits without admission in a hospital (paragraph [0030]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein one of the plurality of values is selected from the group consisting of: a value representing the number of medical specialists that treated the candidate, a value representing the number of inpatient admissions, a value representing the number of chronic diseases for which the candidate was treated, a value representing the number of prescriptions for unique drugs, or a value representing the number of emergency room visits without admission in a hospital as taught by Goetzke with the motivation of ensuring a patient receives quality health care in a cost efficient manner (paragraph [0028]).

In regard to claim 6 (Original), Trusheim and Goetzke teach a method, as per claim 1, for administering reductions in health care costs.

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Goetzke teaches a method wherein the step of generating a result includes generating a first result that indicates whether the first score exceeds the first threshold value, a second result that indicates whether the second score exceeds the second threshold value, and a composite result that represents both the first and second results (paragraphs [0061] and [0079]). Goetzke et al. discloses a method in which outside data (i.e. threshold) is compared to the data of the patient of interest.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the step of generating a result includes generating a first result that indicates whether the first score exceeds the first threshold value, a second result that indicates whether the second score exceeds the second threshold value, and a composite result that represents both the first and second results as taught by Goetzke with the motivation of providing a health plan that is beneficial to both the patient and the payer (i.e. insurer) – paragraph [0076].

In regard to claim 7 (Original), Trusheim and Goetzke teach a method, as per claim 1, for administering reductions in health care costs.

Goetzke teaches a method wherein the step of intervening in the health care regimen of a candidate occurs only if the result of comparison indicates that the first score exceeds the first threshold value and a second result that indicates whether the second score exceeds the second threshold value (paragraphs [0061] and [0068]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the step of intervening in the health care regimen of a candidate occurs only if the result of comparison indicates that the first score exceeds the first threshold value and a second result that indicates whether the second score exceeds the second threshold value as taught by Goetzke with the motivation of providing an individualized health care plan based on the scores of a patients medical profile (paragraph [0067]).

In regard to claim 13 (Currently Amended), Trusheim and Goetzke teach a method, as per claim 1. Trusheim teaches a method wherein the at least one information server is configured for generating a

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plurality of flags, wherein each flag has a status that represents the participant data associated with the intervention candidate (column 14, lines 42 – 47 and column 18, lines 41 – 45).

In regard to claim 14, Trusheim and Goetzke teach the method of claim 13. Trusheim discloses a method wherein one of the plurality of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 – 47). Trusheim discloses a computerized system which tracks all claims as well as all insurance claims. Therefore, it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim.

In regard to claim 16 (Currently Amended), Trusheim and Goetzke teach the method of claim 1. Trusheim teaches a method wherein the graphical user interface that provides the select individual with access to the health care history is presented by an Internet server that provides information that may be displayed on an Internet browser (column 17, lines 14 – 22).

In regard to claim 17 (Original), Trusheim and Goetzke teach a method of claim 16. Trusheim teaches a method wherein the information that may be displayed on an Internet browser includes a plurality of flags, wherein each flag has a status that represents health information of an intervention candidate (column 18, lines 41-45 and Figure 16). Trusheim discloses a method in which a medical event is flagged and a notification is sent to the web server.

In regard to claim 18 (Original), Trusheim and Goetzke teach the method of claim 17. Trusheim teaches a method wherein one of the pluralities of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 – 47). Trusheim et al. discloses a computerized system which tracks all claims as well as all insurance claims. Therefore, it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim.

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In regard to claim 19 (Currently Amended), Trusheim teaches a method for administering reductions in health care costs comprising:

storing in at least one database health information relating to a plurality of health insurance plan participants (column 11, lines 35 – 44);

generating a plurality of flags for each intervention candidate, wherein each flag has a status that represents a health condition of an intervention candidate (column 10, line 50 through column 11, line 3 and column 21, lines 17 – 25 where Trusheim discloses a data repository program which generates a variety of clinical alerts which are equated to flags. A clinical alert is a notification which alerts the caregiver to any ongoing or historical medical problems, thus it is considered a flag); and wherein one of the plurality of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 - 47 where Trusheim discloses a computerized system which tracks all claims as well as all insurance claims, therefore it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim);

storing the health information and flags for each intervention participant in a separate database (column 17, lines 23 – 36); and

permitting select individuals to retrieve and display via a graphical user interface each intervention candidate's health information and flags as stored in the separate database (column 8, lines 10 – 16).

Goetzke discloses a method identifying from stored health information candidates for whom health care costs may be reduced through intervention ("intervention candidates") - paragraph [0026].

The motivation to combine the teachings of Trusheim and Goetzke is discussed in the rejection of claim 1, and incorporated herein.

5. Claims 8 – 9, 11 – 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trusheim et al., herein after Trusheim (U.S. Patent No. 6,385,589 B1) in view of Goetzke et al., herein after Goetzke (U.S. Publication No. 2002/012866A1) in further view of Minturn (U.S. Patent No. 5,692,501)

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In regard to claim 8 (Currently Amended), Trushiem and Goetzke teach a method, as per claim 1, in administering reductions in health care costs.

Minturn teaches a method wherein the graphical user interface facilitates intervening by displaying the result of the comparison that causes a health care provider to contact the at least one eligible intervention candidate in order to recommend a change in the at least one eligible intervention candidate's health care regimen (column 10, lines 47 – 58).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the graphical user interface facilitates intervening by displaying the result of the comparison that causes a health care provider to contact the at least one eligible intervention candidate in order to recommend a change in the at least one eligible intervention candidate's health care regimen as taught by Minturn, within the method of Trusheim and Goetzke, with the motivation of improving participants health by offering periodic monitoring which can thus lead to a decrease in insurance costs (column 9, lines 38 – 43).

In regard to claim 9 (Currently Amended), Trusheim, Goetzke, and Minturn teach a method as per claim 8.

Minturn teaches a method wherein the recommendation includes that the at least one eligible intervention candidate increases physical activity and cardio respiratory fitness (column 17, lines 27 – 29).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the recommendation includes that the candidate increase physical activity and cardio respiratory fitness as taught by Minturn with the motivation of improving their cardiovascular system to maintain a healthy lifestyle (column 17, line 67 through column 18, line 3).

In regard to claim 11 (Currently Amended), Trusheim, Goetzke, and Minturn teach a method as per claim 8.

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Goetzke et al teaches a method wherein the recommendation includes that the at least one eligible intervention candidate enters a substance abuse program (paragraph [0067]). Goetzke et al. discloses a system in which chronic drug use is categorized in the medical profile and can be translated into a treatment. The Examiner interprets this to imply that an indication of chronic drug use can be flagged so that the patient can be placed in a treatment program for substance abuse (paragraph [0068]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the recommendation includes that the at least one eligible intervention candidate enters a substance abuse program as taught by Goetzke, within the method of Trusheim and Minturn, with the motivation of providing an efficient and effective health care program while at the same time reducing costs (paragraph [0026]).

In regard to claim 12 (Currently Amended), Trusheim, Goetzke, and Minturn teach a method as per claim 8.

Goetzke et al. teaches a method wherein the recommendation includes that the candidate consults a mental health practitioner (paragraph [0067]). Goetzke et al. discloses a system in which depression (which is included under the broad category of mental health) is categorized in the medical profile and can be translated into a treatment. The Examiner interprets this to imply that an indication of mental health issues can be flagged so that the patient can be placed in a treatment program for mental health (paragraph [0068]).

The motivation for combining the teachings of Trusheim, Goetzke, and Minturn is discussed in the rejection of claim 11, and incorporated herein.

In regard to claim 15 (Currently Amended), Trusheim and Goetzke teach a method, as per claim 1, in administering reductions in health care costs.

Minturn teaches a method wherein the second score further indicates the potential for health care cost reduction of the intervention candidate as determined relative to other participants in the health insurance plan (column 12, lines 24 – 25 and column 30, lines 43 – 65).

The motivation for combining the teachings of Trusheim, Goetzke, and Minturn is discussed in the rejection of claim 8, and incorporated herein.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trusheim, Goetzke, and Minturn as applied to claim 8 above, and further in view of Chao (U.S. Publication No. 2006/0178915 A1).

In regard to claim 10 (Currently Amended), Trusheim, Goetzke, and Minturn teach a method as per claim 8.

Chao teaches a method wherein the recommendation includes that the at least one eligible intervention candidate switch prescriptions from a brand name drug to a generic drug (paragraph [0089]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the recommendation includes that the candidate switch prescriptions from a brand name drug to a generic drug as taught by Chao, within the method of Trusheim, Goetzke, and Minturn, with the motivation of providing accessible and affordable medication to patients through a health care plan (paragraph [0015]).

Response to Arguments

7. Applicant's arguments filed November 25, 2008 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed November 25, 2008.

In response to the Applicant's argument, it is respectfully submitted that the Examiner has applied new passages and new citations to the amended claims. The Examiner notes that the amended limitations were not in the previously pending claims; as such, Applicant's remarks with the regard to the application of over Trusheim, Goetzke, Minturn, and Chao are addressed in the above Office Action.

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Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KKR

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626